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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,279	07/18/2001	Kazumi Iijima	114474-13-FESI00001	5027
38492	7590	08/09/2005	EXAMINER	
WILLKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099				AUGHENBAUGH, WALTER
ART UNIT		PAPER NUMBER		
				1772

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/647,279	IIJIMA, KAZUMI
	<b>Examiner</b>	<b>Art Unit</b>
	Walter B. Aughenbaugh	1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 July 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,6 and 10 is/are pending in the application.
  - 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 11, 2005 (Amdt. D) has been entered.

### ***Acknowledgement of Applicant's Amendments***

2. The amendments made in claim 1 in the Amendment filed July 11, 2005 (Amdt. D) have been received and considered by Examiner.
3. New claim 10 presented in Amdt. D has been received and considered by Examiner.
4. The cancellation of claims 3, 5 and 7-9 in Amdt. D has been acknowledged by Examiner.

## ***WITHDRAWN REJECTIONS***

### ***Claim Rejections - 35 USC § 112***

5. The 35 U.S.C. 112 rejection of claim 7 made of record in paragraph 6 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's cancellation of claim 7 in Amdt. D.

### ***Claim Rejections - 35 USC § 102***

6. The 35 U.S.C. 102 rejection of claim 1 that was repeated in paragraph 4 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's amendments in claim 1 in Amdt. D.

7. The 35 U.S.C. 102 rejection of claim 5 that was repeated in paragraph 4 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's cancellation of claim 5 in Amdt. D.

***Claim Rejections - 35 USC § 103***

8. The 35 U.S.C. 103 rejection of claim 3 that was repeated in paragraph 5 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's cancellation of claim 3 in Amdt. D.

9. The 35 U.S.C. 103 rejection of claims 7 and 8 made of record in paragraph 7 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's cancellation of claims 7 and 8 in Amdt. D.

10. The 35 U.S.C. 103 rejection of claim 9 made of record in paragraph 8 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's cancellation of claim 9 in Amdt. D.

***NEW REJECTIONS***

***Claim Rejections - 35 USC § 103***

11. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Porfano et al.

In regard to claim 1, Moncada et al. teach a syringe barrel (the combination of syringe barrel, item 84 and adapter, item 80, having a generally continuous surface at the junction of the syringe and the barrel and the adapter, see Fig. 5) comprising a nozzle portion (adapter body, item 20, Fig. 1 and 2 and adapter, item 80, Fig. 5) in which an outer cylinder (flanges, item 116, Fig. 5 and corresponding unlabelled flanges in Fig. 1) and an inner cylinder (cylindrical portion,

item 30, Fig. 1 and male Luer lock connector portion, item 106, Fig. 5 ) are formed and a luer lock portion (the space between item 30 and the unlabelled flange in Fig. 1 that corresponds to item 116 of Fig. 5 and the space between items 106 and 116 in Fig. 5) formed in the nozzle portion and between an inner peripheral surface of the outer cylinder and an outer peripheral surface of the inner cylinder (Fig. 1 and 5) (col. 3, lines 62-67, col. 4, lines 2-4, col. 5, line 48- col. 6, line 20). Moncada et al. teach a Luer lock connector having ears (item 122) on the male Luer lock portion of the needle mount (item 94) and threads (item 124) on the female Luer lock portion (item 118) (col. 6, lines 7-16 and Fig. 5). Moncada et al. teach that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23). The portion of the female Luer lock portion (item 118) that has threads (item 124) corresponds the outer cylinder as claimed; Moncada et al. therefore teach that the inner peripheral surface of the outer cylinder contains a helically continuous screw thread.

Moncada et al. fail to explicitly teach that the surface of the screw thread or screw root portion formed between adjacent ridges of the screw thread specifically has a sandblasted surface and that the outer cylinder is made of cyclic polyolefin resin.

However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface (a sandblasted surface falls within the scope of this teaching) for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to

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have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface (including a sandblasted surface) on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

Furthermore, Porfano et al. teach a syringe barrel (item 12) that is made of cyclic polyolefin copolymer resin (col. 6, lines 48). Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48). Therefore, one of ordinary skill in the art would have recognized to use cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. (including the outer cylinder of the syringe barrel of Moncada et al.) since cyclic polyolefin copolymer resin is a well known material for syringe barrels as taught by Porfano et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface (including a sandblasted surface) on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al. and to have used cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. (including the outer cylinder of the syringe barrel

of Moncada et al.) since cyclic polyolefin copolymer resin is a well known material for syringe barrels as taught by Porfano et al.

In regard to claim 10, Moncada et al. fail to explicitly teach that the inner cylinder is made of cyclic polyolefin resin and that the outer peripheral surface of the inner cylinder has a sandblasted surface.

However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface (a sandblasted surface falls within the scope of this teaching) for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to have formed a sandblasted surface on the outer peripheral surface of the inner cylinder when required depending on the desired end use of the product as taught by Moncada et al. in order to increase frictional engagement between the outer peripheral surface of the inner cylinder and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

Furthermore, Porfano et al. teach a syringe barrel (item 12) that is made of cyclic polyolefin copolymer resin (col. 6, lines 48). Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48). Therefore, one of ordinary skill in the art would have recognized to use cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. (including the inner cylinder of the syringe barrel

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of Moncada et al.) since cyclic polyolefin copolymer resin is a well known material for syringe barrels as taught by Porfano et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed a sandblasted surface on the outer peripheral surface of the inner cylinder when required depending on the desired end use of the product as taught by Moncada et al. in order to increase frictional engagement between the outer peripheral surface of the inner cylinder and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al. and to have used cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. (including the inner cylinder of the syringe barrel of Moncada et al.) since cyclic polyolefin copolymer resin is a well known material for syringe barrels as taught by Porfano et al.

*Response to Arguments*

12. Applicant's arguments regarding Moncada et al. in regard to the rejection of claim 1 presented on pages 4-5 of Amdt. D have been fully considered but are not persuasive. Applicant argues that the "mere statement" that the modification to the syringe barrel of Moncada et al. proposed in the 35 U.S.C. 103(a) rejection of now cancelled claim 3 in the previous Office Action mailed January 11, 2005 "would have been obvious to one of ordinary skill in the art at the time the invention" is not sufficient to establish a prima facie case of obviousness, but this statement is supported with objective reasoning: as stated in this Office Action in the 35 U.S.C. 103(a) rejection of claim 1,

since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface (a sandblasted surface falls within the scope of this teaching) for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would

have recognized to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed any type of roughened surface (including a sandblasted surface) on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

Applicant speculates in the paragraph bridging pages 4 and 5 that teeth are unsatisfactory for syringes, but the Office Action does not propose forming teeth between adjacent ridges of the screw thread of Moncada et al. but rather to forming any type of roughened surface (including a sandblasted surface) on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion.

13. Applicant argues that there is no motivation to combine Moncada et al. with Porfano et al. in the first full paragraph of page 5 of the Amdt. D. One of ordinary skill in the art would have recognized to consult Porfano et al. to determine the particular material to use for the syringe barrel because Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as a syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48), as made of record in paragraph 8 of the previous Office Action mailed January 11, 2005. Porfano et al. plainly teaches that cyclic polyolefin copolymer is a suitable material for use as a syringe barrel; therefore, one of ordinary skill in the art would have recognized to have used the cyclic polyolefin copolymer of Porfano et al. as the material of the syringe barrel of Moncada et al.

14. Applicant's argument in the second full paragraph of page 5 of Amdt. D. regarding the "formed by blast treatment" recitation is moot since this recitation is not in any of the pending claims.

***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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08/06/05

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